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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

AZUR PHARMA INC., Plaintiff, v. TRIGEN LABORATORIES, INC., Defendant.	Civil Action No. 10 CV 207 (NRB) Hon. Naomi Rice Buchwald **TRIGEN LABORATORIES, INC.'S MEMORANDA OF LAW IN OPPOSITION TO AZUR'S MOTION FOR PRELIMINARY INJUNCTION**

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Defendant TRIGEN Laboratories, Inc. ("TRIGEN") hereby opposes Plaintiff Azur Pharma Inc.'s ("Azur") Motion for a Preliminary Injunction ("PI Motion").

INTRODUCTION

Azur and TRIGEN compete in the market for pre-natal vitamins. Azur sells three prescription pre-natal vitamins relevant to its PI Motion: Gesticare®, Gesticare® with DHA, and Gesticare® with DHA NF (collectively "the Gesticare® Products"). Azur does not have any intellectual property rights the Gesticare® Products.[1,2] TRIGEN offers (or plans to offer) low cost alternatives to each of the Gesticare® Products, namely Taron™ EC Calcium[3] ("Taron™"), Taron™ EC Calcium DHA ("Taron™ DHA"), and Folivane™ EC Calcium DHA ("Folivane™") (collectively "the TRIGEN Products"). Both the Gesticare® Products and the TRIGEN Products are prescription pre-natal vitamins.

The Gesticare® Products are the "brand products" and the TRIGEN Products are low-cost alternatives to the brand products. Drug publishing services, such as Medi-Span, First Databank, Red Book, and Gold Standard, identify alternatives[4] or substitutes to brand product pre-natal vitamins such as the ones at issue in this litigation. These

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[1] Azur admitted this in response to a direct question from Judge Buchwald during the hearing on Azur's Motion for a Temporary Restraining Order.

[2] Azur argues "[t]his is a case of one company leaching on to the accomplishments of another for its own benefit." PI Memo ("D.I. 16"), p. 2. Despite Azur's passionate plea, "[i]t is not illegal to copy a product that is unprotected by a patent." *Graceway Pharm. v. Rivers Edge Pharm.*, 2009 WL 3753586, *10 (N.D.Ga. 2009) citing *Cooper Indus. v. Leatherman Tool Group,* 532 U.S. 424, 441 (2001) ("[C]opying of the functional features of an unpatented product is lawful.").

[3] TRIGEN has not yet begun sales of its Taron™ EC Calcium ("Taron™") product.

[4] Azur haphazardly alleges that drug publishing services identify *generic* (D.I. 16, p.4; Kelly Declaration ("D.I. 17") ¶ 29), *equivalent* (D.I. 16, p. 6; D.I. 17, ¶¶ 14, 28), *alternative* (D.I. 16, p. 6; D.I. 17, ¶¶ 17, 28, 29), and *identical* (D.I. 17, ¶ 45) drugs. Each of these terms (generic, equivalent, alternative, and identical) have specific meanings. On information and belief, drug publishing services identify alternative or substitute drugs.

alternatives are said to be "linked" to the associated brand product. At least one of the drug publishing services has linked the TRIGEN Products with the Gesticare® Products.

As a result of this link, some pharmacists may properly fill a prescription for Gesticare® DHA with Taron™ DHA; or a prescription for Gesticare® DHA NF with Folivane™. Some pharmacist have been filling prescriptions for Gesticare® Products with TRIGEN Products and Azur has lost a small portion of its market to TRIGEN. In an effort to "eliminate the competition," Azur filed this suit, its previous Motion for a Temporary Restraining Order and Preliminary Injunction, and now its latest PI Motion.

The TRIGEN Products offer both physicians and consumers a choice between the higher priced brand Gesticare® Products and the low cost alternative TRIGEN Products. A prescribing physician can insist on the brand product by indicating on the prescription "Dispensed as Prescribed." Alternatively, the consumer can insist on the brand product by indicating her preference when the prescription is filled. Azur's lawsuit and its PI Motion attempt to preclude competition to ensure that it can continue to charge monopoly prices for its Gesticare® Products. Without a low cost alternative to the Gesticare® Products, many pregnant women will be unable to afford biphasic prenatal vitamins.

NATURE AND STAGE OF PROCEEDINGS

On January 12, 2010, Azur filed a complaint in this Court against TRIGEN under Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B). TRIGEN timely filed its answer on February 4, 2010. On February 16, 2010, counsel for Azur sent an Order to Show Cause, a Memorandum of Law in Support of Plaintiff's Motion for a Preliminary Injunction and Temporary Restraining Order ("PI/TRO Motion"), a cover letter, and related documents directly to Judge Buchwald and TRIGEN's counsel. Judge Buchwald

held a TRO hearing and denied Azur's requested TRO. During the TRO hearing, Judge Buchwald identified a number of "problems" with Azur's PI/TRO Motion, but ordered the parties to brief the PI portion of the motion. Rather than try to revive its flawed PI/TRO Motion, Azur withdrew the PI portion of its PI/TRO Motion, updated its declarations to address some of the deficiencies, and filed its latest PI Motion and supporting memorandum ("PI Memo") on March 19th.

SUMMARY OF THE ARGUMENT

Azur's PI Motion asks this Court to: (i) alter the status quo by preventing TRIGEN from selling the Taron™ DHA and Folivane™ products it currently sells, and (ii) grant Azur the ultimate relief it seeks in this matter. As such, Azur's PI motion is subject to a higher standard and Azur must show: (a) it will suffer irreparable harm in the absence of an injunction, and (b) either (i) a clear or substantial likelihood of success, or (ii) that extreme or very serious damage will result from a denial of preliminary relief. Azur, has not, and cannot show any of these.

Azur cannot show that it will suffer irreparable harm because Azur can be adequately compensated (financially) for any loss it may incur. Azur alleges that (in some circumstances) TRIGEN's Products are being dispensed in place of Azur's prescribed Gesticare® Products. If this is the case, and Azur were to prevail at trial, the total sales of the TRIGEN Products could be used to determine a monetary award that adequately compensates Azur for its lost sales. Since a monetary award can adequately compensated Azur, there is no reason why the extraordinary equitable remedy of a preliminary injunction should be granted.

Azur has also failed to show a clear or substantial likelihood of success. Azur brings this case under Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B). In order for Azur to prevail, it must show TRIGEN made a false or misleading statement, the false statement was material, *and* the statement was used in commercial advertising or promotion. While Azur alleges a false statement or two, Azur never shows (or even alleges) that the alleged false statements were material or used in commercial advertising or promotion (*i.e.,* (i) does no more than propose a commercial transaction, (ii) intended to influence consumers to purchase the TRIGEN Products, *and* (iii) disseminated sufficiently to the relevant purchasing public to fall under the Lanham Act). This failure is fatal to Azur's PI Motion.

Moreover, Azur cannot argue that extreme or very serious damage will result from a denial of preliminary relief. The only harm that may come from denying Azur's PI Motion is that Azur may lose some sales or be forced to lower the prices of its Gesticare® Products. On the other hand, denying Azur's PI motion will enable TRIGEN to continue to offer the low cost TRIGEN Products to pregnant and lactating women who simply cannot afford Azur's higher priced Gesticare® Products.

STATEMENT OF FACTS

The facts relevant to this opposition are set forth in the accompanying (i) Kevin Hudy Declaration; (ii) Aaron Barkley Declaration; (iii) Kristen McHenry Declaration; and (iv) David Ko Declaration, submitted herewith, which are incorporated by reference.

ARGUMENT

I. A HIGHER STANDARD APPLIES TO AZUR'S PRELIMINARY INJUNCTION MOTION

A. Second Circuit Standards for Preliminary Injunction Motions

"The Second Circuit recognizes a preliminary injunction as 'one of the most drastic tools in the arsenal of judicial remedies' that should be granted only in extraordinary circumstances." *Amusement Indus. v. Citigroup Markets Realty Corp.*, 2009 Bankr. LEXIS 3941, 44 (S.D.N.Y. 2009) (citing *Hanson Trust PLC v. SCM Corp.*, 774 F.2d 47, 60 (2d Cir. 1985)). "[A] preliminary injunction is an extraordinary and drastic remedy, one that should not be granted unless the movant, *by a clear showing*, carries the burden of persuasion." *Mazurek v. Armstrong*, 520 U.S. 968, 972 (1997); *Grand River Enter. Six Nations, Ltd. v. Pryor*, 481 F.3d 60, 66 (2d Cir. 2007).

Ordinarily, to obtain a preliminary injunction in the Second Circuit, the movant "must show that: (a) it will suffer irreparable harm in the absence of an injunction, and (b) either (i) likelihood of success on the merits or (ii) sufficiently serious questions going to the merits to make them a fair ground for litigation and a balance of hardship tipping decidedly in the movant's favor."[5] *Amusement Indus.*, 2009 Bankr. LEXIS 3941 at 45; *Tom Doherty Assocs. v. Saban Entm't, Inc.*, 60 F.3d 27, 33 (2d Cir. 1995). Under the "likelihood of success on the merits" standard, the movant only needs to "make a showing that the probability of his prevailing is better than fifty percent. There may remain considerable room for doubt." *Abdul Wali v. Coughlin*, 754 F.2d 1015, 1025 (2d

[5] The Second Circuit has recently affirmed the "serious question" portion of this circuit's general standard for preliminary injunctions. *Citigroup Global Mkts., v. VCG Special Opportunities Master Fund Ltd.*, 2010 U.S. App. LEXIS 5025, 12-13 (2d Cir. 2010). However, none of the limited exceptions to the general standard (*i.e.*, those that would require the court to apply the higher standard) were present in that case. *Id.* at 12.

Cir. 1985) (citing *Hamilton Watch Co. v. Benrus Watch Co.*, 206 F.2d 738, 740 (2d Cir. 1953)). Azur mistakenly argues that the "likelihood of success on the merits" standard for a preliminary injunction should be applied to its PI Motion.[6]

Azur fails to address, or mention, the Second Circuit's requirement that "the movant [ ] meet a *higher standard* where: (i) an injunction will alter, rather than maintain, the status quo, or (ii) an injunction will provide the movant with substantially all the relief sought and that relief cannot be undone even if the defendant prevails at a trial on the merits." *Tom Doherty Assocs.*, 60 F.3d at 33-34 (emphasis added); See *Citigroup Global Mkts., v. VCG Special Opportunities Master Fund Ltd.*, 2010 U.S. App. LEXIS 5025, 12-13 (2d Cir. 2010). If either of these factors are present, "the moving party must show a 'clear' or 'substantial' likelihood of success," or that "extreme or very serious damage will result from a denial of preliminary relief." *Tom Doherty Assocs.*, 60 F.3d at 34. The "clear" or "substantial" requirement thus alters the traditional consideration and requires that the movant demonstrate a greater likelihood of success. See *SEC v. Unifund SAL*, 910 F.2d 1028, 1039 (2d Cir. 1990). Under the "substantial likelihood of success on the merits" standard, the movant must show its "cause is considerably more likely to succeed than fail." *Abdul Wali*, 754 F.2d at 1026. By requiring this higher standard, "we may content ourselves in the knowledge that injunctive relief will not be precipitously granted in cases where the grant may serve to provide all the relief sought on the merits." *Id.*

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[6] Azur argues that it only needs to show "the threat of irreparable harm" (D.I. 16, p. 5), *i.e.*, a less demanding standard than either of the cases cited by Azur. The *Doherty* court required the movant to show "that it *will suffer* irreparable harm in the absence of an injunction." *Tom Doherty Assocs.*, 60 F.3d at 33 (emphasis added). The *Malletier* court required the movant to show "the *likelihood* of irreparable injury." *Louis Vuitton Malletier v. Burlington Coat Factory Warehouse Corp.*, 426 F.3d 532, 537 (2d Cir. 2005) (emphasis added).

Moreover, when the higher standard for a preliminary injunction is required, a preliminary injunction is not available to a movant under the "serious questions/balance of hardship" criteria. *Ponterio v. Kaye*, 2007 U.S. Dist. LEXIS 4105, *42 n. 29 (S.D.N.Y. 2007) (*citing Tom Doherty Assocs.*, 60 F.3d at 34). Therefore, when the movant seeks a preliminary injunction that alters the status quo or provides the movant with substantially all the relief sought (and that relief cannot be undone even if the defendant prevails at a trial on the merits); the movant must show: (a) it will suffer irreparable harm in the absence of an injunction, and (b) either (i) a clear or substantial likelihood of success, or (ii) that extreme or very serious damage will result from a denial of preliminary relief.

B. The Preliminary Injunction Requested by Azur will Alter the Status Quo and Provide Azur with Substantially all of the Relief It Seeks

Azur's PI Motion requests an order preventing TRIGEN "from falsely marketing, promoting, advertising, offering for sale, . . . [the TRIGEN Products] that [TRIGEN] currently distributes." PI Motion ("D.I. 15"), p. 2, PI Memo ("D.I. 16"), p.1. TRIGEN currently enjoys the freedom to market, promote, advertise, offer for sale, sell, . . . the TRIGEN Products and does each of these for the Taron™ DHA and Folivane™ products. Rather than maintaining the status quo, Azur's PI Motion seeks to alter the status quo by forbidding TRIGEN from continuing its current activities. Azur's PI Memo also requests an order commanding the recall of the TRIGEN Products. D.I. 16, p. 2. For at least this reason, Azur's motion is subject to the higher standard.

In this litigation, Azur's requests a permanent injunction enjoining TRIGEN from marketing or selling the TRIGEN Products, forcing TRIGEN to take actions to delink the TRIGEN Products from the Gesticare® Products, and recalling the TRIGEN Products

from the marketplace. Azur's Amended Complaint ("D.I. 13"), p. 8-9. While Azur's PI Motion does not require TRIGEN to "delink" the TRIGEN Products from the Gesticare® Products, the link would be meaningless if TRIGEN were enjoined from selling its products. The relief requested by Azur in its PI Motion is substantially all of the relief Azur requests in this litigation. Additionally, if TRIGEN is forced to recall and stop selling its products, TRIGEN's products would lose credibility in the marketplace, TRIGEN would lose credibility with its customers, and it would be extremely difficult, if not impossible, for TRIGEN to reintroduce those products after it prevails in a trial on the merits. Declaration of Kevin Hudy, ("Hudy Decl.") ¶¶ 19 - 21. For this additional reason, Azur's PI Motion is subject to a higher standard because it provides Azur with all of the relief sought which cannot be undone after trial.

II. AZUR HAS NOT SHOWN IRREPARABLE HARM

A. Second Circuit Standards for Irreparable Harm

In the Second Circuit, "[i]rreparable harm is the single most important prerequisite for the issuance of a preliminary injunction [and] the moving party must first demonstrate that such injury is likely before the other requirements for the issuance of an injunction will be considered." *Freedom Holdings, Inc. v. Spitzer*, 408 F.3d 112, 114 (2d Cir. 2005). "Irreparable harm 'means an injury for which a monetary award cannot bring adequate compensation.'" *Excell v. Fischer*, 2009 U.S. Dist. LEXIS 88506, *45 (N.D.N.Y. 2009) (citing *Jackson Dairy, Inc. v. H.P. Hood & Sons, Inc.*, 596 F.2d 70,72 (2d Cir. 1979) ("where money damage is adequate compensation a preliminary injunction will not issue.")).

Moreover, "[a] claim of irreparable harm is undercut by a party's unreasonable delay in seeking injunctive relief." *Amusement Indus.*, 2009 Bankr. LEXIS 3941, 49

(citing *Tough Traveler, Ltd. v. Outbound Products*, 60 F.3d 964, 968 (2d Cir. 1995) ("[A]ny such presumption of irreparable harm is inoperative if the plaintiff has delayed either in bringing suit or in moving for preliminary injunctive relief. . . . standing alone [the delay may] . . . preclude the granting of preliminary injunctive relief, because the failure to act sooner undercuts the sense of urgency that ordinarily accompanies a motion for preliminary relief and suggests that there is, in fact, no irreparable injury.") (internal citations and quotations omitted.)). "A party's delay in seeking relief, in the face of potential harm caused by such a delay, vitiates a party's claim that such harm is irreparable." *Amusement Indus.*, 2009 Bankr. LEXIS 3941, 50.

B. There is no Compelling Reason for the Extraordinary Equitable Remedy of a Preliminary Injunction

Drug publishing services, such as Medi-Span, First Databank, Red Book, and Gold Standard identify equivalent pharmaceutical products. Azur's Original Complaint, ("D.I. 1") ¶ 4. At least one of these drug publishing services has identified TRIGEN's products as alternatives to the Gesticare® products and "linked" the products. As a result of this link, pharmaceutical supply companies have contacted TRIGEN to purchase the TRIGEN Products. Hudy Decl. ¶ 13. According to Azur, TRIGEN's products are sold to customers when a pharmacist is presented with a prescription for a Gesticare® Product and the pharmacist dispenses a TRIGEN Product instead of the prescribed Gesticare® Product. As such, it is a relatively easy matter to determine Azur's lost sales, every sale of a TRIGEN Product would have been a sale of a Gesticare® Product. If Azur should prevail at trial, adequate financial compensation could be provided to Azur. "[W]hen a party can be fully compensated for financial loss by a money judgment, there is simply no compelling reason why the extraordinary equitable remedy of a preliminary injunction

should be granted." *Borey v. Nat'l Union Fire Ins. Co. of Pittsburgh*, 934 F.2d 30, 34 (2d Cir. 1991) (citing *Jackson Dairy, Inc. v. H.P. Hood & Sons, Inc.*, 596 F.2d 70, 72 (2d Cir. 1979).

While Azur alleges that its goodwill will be harmed, it fails to provide any factual basis for its allegation. Kelly Declaration, ("D.I. 17") ¶ 48. "[S]omething more than [Azur's] mere subjective belief that [it] is injured or likely to be damaged is required before [it] will be entitled even to injunctive relief." *Johnson & Johnson v. Carter-Wallace, Inc.*, 631 F.2d 186,189 (2d Cir. 1980). In light of the clear differences in the colors and the markings on the packages of the Gesticare® Products and the TRIGEN Products, it is doubtful that Azur will suffer any loss of its goodwill.

C. Azur's Delay in Bringing this Case and Its Preliminary Injunction Motion Shows there is no Irreparable Harm

Azur's General Manager, Mr. Michael Kelly, admits that Azur learned of TRIGEN's plans to market an alternative to the Gesticare® Products on or about September 1, 2009 - *i.e.*, over six months ago. D.I. 17 ¶ 13. Despite this knowledge, Azur failed to file its original complaint until January 12, 2010 - a delay of over four months. D.I. 1. This is but one of the many delays attributable to Azur.

On September 3, 2009, counsel for Azur sent a letter to TRIGEN claiming TRIGEN's labels on its proposed Taron™ DHA product violated the Food Allergen Labeling & Consumer Protection Act. Wagner Declaration ("D.I. 20"), Ex. D. Azur's September 3rd letter threatened to "pursue all remedies available to it at law and in equity, including commencing a lawsuit seeking injunctive relief" if Azur did not receive confirmation from TRIGEN within five (5) days. *Id.*, p. 2. The September 8th deadline passed without Azur filing its lawsuit or seeking injunctive relief.

Again, on September 24, 2009, counsel for Azur sent a letter to TRIGEN threatening to take action unless TRIGEN responded within five (5) days. D.I. 20, Ex. E. The September 29th deadline passed without Azur seeking injunctive relief.

Azur then waited almost three months before it sent two additional letters to TRIGEN, both on the same day. D.I. 20, Exs. F, G. During these three months TRIGEN continued to manufacture the TRIGEN Products and to make other preparations to bring its products to market. Hudy Decl. ¶¶ 22-24: Ko Declaration ("Ko Decl.") Exs. A, B, E, G, I. Again Azur threatened to file a lawsuit and seek injunctive relief within five (5) days. D.I. 20, Exs. F, G. In each of these letters, Azur also threatened to "take such other appropriate action, potentially including notification to regulatory authorities, in the event that a laboratory assay and dissolution analysis of [Taron™ DHA and Folivane™] specifications reveals that other significant differences between the products exist." D.I. 20, Ex. F, p. 2; Ex. G, p. 2. The December 22, 2009 deadline passed without Azur filing a lawsuit or seeking injunctive relief.

On January 12, 2010, a full four months after Azur learned of TRIGEN's plans to enter the market, Azur filed a complaint with this Court. D.I. 1. Azur did not include a motion for a temporary restraining order, or a motion for a preliminary injunction with its complaint. *Id.* Instead, another month passed before Azur sought a temporary restraining order and a preliminary injunction claiming an "emergent need for immediate relief" and requesting a hearing within 24 hours. Judge Buchwald held the TRO hearing requested by Azur and denied the requested TRO. Judge Buchwald order the parties to brief Azur's PI motion. TRIGEN's counsel worked with Azur's counsel to develop an aggressive schedule to comply with Judge Buchwald's order. Rather than brief the PI portion of

Azur's TRO/PI motion, Azur withdrew its earlier PI motion on February 25, 2010, updated its declarations, and re-filed its new PI Motion in March.

Azur's four month delay in filing its initial complaint, its failure to include a TRO/PI Motion with its initial complaint, its failure to follow through with its initial TRO/PI Motion, and its subsequent delay in re-filing its PI Motion each undercuts Azur's argument that it faces irreparable harm. *Amusement Indus.*, 2009 Bankr. LEXIS 3941, 50 Additionally, TRIGEN's efforts to produce and market the TRIGEN Products during Azur's delays provide additional reasons why the requested preliminary injunction should be denied. *Tom Doherty Assocs.*, 60 F.3d at 39

III. AZUR HAS FAILED TO SHOW A LIKELIHOOD OF SUCCESS ON THE MERITS

A. Second Circuit Standards for Likelihood of Success on the Merits

Azur brings this case under Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B). A false advertising claim under Section 1125(a)(1)(B) of the Lanham act requires the plaintiff establish: (1) the defendant made a false statement; (2) the false statement was used in commercial advertising or promotion; and (3) the "advertising or promotion misrepresents the nature, characteristics, qualities, or geographic origin of an inherent quality or characteristic of Plaintiff's or Defendant's products." *Chamilia v. Pandora Jewelry*, 2007 U.S. Dist. LEXIS 71246, *16 (S.D.N.Y. 2007).

1. Azur Has Failed to Show A Material False Statement

To demonstrate that a statement is false, the movant may show either: (1) the advertisement is literally false, or (2) while the advertisement is literally true, it is nonetheless likely to deceive or confuse customers. *Id.*; *Nat'l Basketball Ass'n v. Motorola, Inc.*, 105 F.3d 841, 855 (2d Cir. 1997). In addition, the movant must show that

the false statement was material, *i.e.*, that the misrepresentation is likely to influence the consumer's purchasing decision. *Nat'l Basketball Ass'n*, 105 F.3d at 855.

In its PI Memo, Azur argues that TRIGEN makes two claims regarding the TRIGEN Products that are "literally false as a factual matter." D.I. 16, p. 5. These are: (1) that the TRIGEN Products are biphasic; and (2) "that the Trigen Products contain the identical ingredients and ingredients strengths as the Gesticare® Products." *Id.* For support, Azur cites to the Bakhshi[7] declaration/exhibits and the Reuther declaration.

The Bakhshi declaration alleges: (1) the Taron™ DHA and Folivane™ tablets are not biphasic (Bakhshi Declaration ("D.I. 18"), ¶¶ 21-27); (2) the Taron™ DHA tablets do not contain the proper amounts of four ingredients (D.I. 18, ¶ 33); and (3) the Folivane™ tablets do not contain the proper amounts of two ingredients (D.I. 18, ¶ 34). The Reuther Declaration alleges that the claimed amount of DHA is incorrect and the labels do not include EPA. Reuther Declaration ("D.I. 19"), ¶¶ 9-11, 14-16, 18-20. These allegations are questionable, immaterial and, do not warrant a preliminary injunction.

a. Bakhshi's Biphasic Testing is Inappropriate and Entitled to No Weight

Azur's expert, Mr. Bakhshi admits that there is no USP approved definition for biphasic with respect to biphasic multivitamin/mineral tablets. Barkley Declaration ("Barkley Decl.") ¶ 32. He also testified that the procedures LaboVal ran to test the biphasic characteristics of the TRIGEN Products: 1) do not follow an approved USP monograph; 2) were specifically developed and validated for the Gesticare® Products; 3)

[7] TRIGEN does not believe that Mr. Bakhshi qualifies as an expert under FRE 702 Barkley Decl. *passim*. As such, TRIGEN reserves the right to challenge Mr. Bakhshi's qualifications if Azur attempts to use Mr. Bakhshi's opinions in any other portion of this litigation.

have not been modified or validated for the TRIGEN Products; 4) could not be used for release testing of TRIGEN Products; and 5) gave inconsistent results for the three tests Azur ran on identical Taron™ DHA products (*i.e.*, tablets from the same lot). Barkley Decl. ¶¶ 30-41, 64; D.I. 18, Exs. E - H. Yet despite the overwhelming evidence to the contrary, Azur claims that its testing "conclusively" proves the TRIGEN Products are not biphasic. D.I. 16, p. 5. LaboVal's tests are not the result of reliable principles and methods and do not meet the requirements of the Federal Rules of Evidence 702. Barkley Decl. *passim.* Moreover, Viva successfully tested the delayed-release characteristics of the enteric coated calcium granules in a method it developed for the TRIGEN Products. Barkley Decl. ¶ 42-43; Ko Decl. ¶¶ 18-20.

b. The Inconsistencies Contained in Bakhshi's Assay Testing Results Raise Questions Concerning its Reliability and Materiality

A comparison of the Bakhshi declaration and his deposition testimony show inconsistencies in the testing methods allegedly used, the ingredients tested, the correct application of USP acceptance criteria, and highlight numerous other errors that invalidate the test results. Barkley Decl. ¶¶ 50-54, 64. For example, Mr. Bakhshi claims that LaboVal conducted its Assay Tests in accordance with "USP Edition 32: Oil- and Water- Soluble Vitamins" to determine a chemical analysis of the Taron™ DHA product (three different Assay Tests) and the Folivane™ product (one Assay Test). D.I. 18, ¶ 30. However, at his deposition Mr. Bakhshi stated that the correct Assay Test for the Taron™ DHA and Folivane™ products is actually USP Edition 32: Oil- and Water-Soluble Vitamins *with Minerals* Capsule. Barkley Decl. ¶ 50. The USP section relied on by Mr. Bakhshi affirms that the Oil- and Water- Soluble Vitamin Assay Test is not

applicable to vitamins which contain minerals. D.I. 18, Ex. I, second column, 7th line. Mr. Bakhshi was unable to explain why LaboVal used the wrong Assay Test. Barkley Decl. ¶ 50.

LaboVal performed three different Assay Tests on the Taron™ DHA product and the results of those tests are provided in the exhibits to Mr. Bakhshi's Declaration. D.I. 18, ¶ 33, Exs. J, F, and G. Assuming the results of the three tests were accurate, Mr. Bakhshi claimed that the amounts of Vitamin B12, Thiamin HCL[8], Vitamin C (ascorbic acid), and iodine where outside the ranges permitted by the USP, which he claimed were 90% - 125%. D.I. 18, ¶ 33. However, during Mr. Bakhshi's deposition he admitted that he had misread the USP guidelines and the allowable USP variation for Thiamin, B12 (cyanocobalamin) and Vitamin C (ascorbic acid) is 90.0% - 150%. Barkley Decl. ¶ 52. See D.I. 18, Ex. K, p. 2155, second column, lines 6 - 15. Under the proper USP ranges,[9] LaboVal's testing showed the proper amounts of Thiamin and Vitamin C.

The Food and Drug Administration ("FDA") Recommended Daily Allowance ("RDA") for pregnant women is 2.6 µg for Vitamin B12 and 220 µg for Iodine. Barkley Decl. ¶ 54. The label for the Taron™ DHA product indicates that each tablet contains 8 µg of B12 (over three times the RDA) and 150 µg of Iodine (approximately ⅔ of the RDA). Hudy Decl. Ex. A. LaboVal's testing allegedly showed that the amount of Vitamin B12 in three Taron™ DHA samples was: 2.35 µg, 2.95 µg, and not detected.

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[8] Mr. Bakhshi claims that the LaboVal testing found Thiamin HCL in each Assay Test for the Taron™ DHA products and the Assay Test for Folivane. D.I. 18, ¶ 33, Exs. F, G, H, and J. However, neither the Taron™ DHA product nor the Folivane™ product contain Thiamin HCL. Instead both products contain Thiamin Mononitrate. Mr. Bakhshi could not explain this error in LaboVal's Assay Testing. Barkley Decl. ¶ 53.

[9] Mr. Bakhshi also admits that Ex. K of his declaration is an outdate version of the ranges. Barkley Decl. ¶ 52. Version 32 contains the same ranges for the ingredients at issue except for the upper limit of Iodine. *Id.*

D.I. 18, ¶ 33, Exs. F, G, and J. Even if we were to believe LaboVal's testing, in two of the three tests, the tablets contained approximately the RDA amount of B12. *Id.* Additionally, many women obtain sufficient amounts of B12 through a healthy and well-rounded diet. Barkley Decl. ¶ 54. LaboVal's testing allegedly showed that the amount of iodine for the three Taron™ DHA samples was: 121 µg, 133 µg, and 212 ug. *Id.* Even if the full amount of iodine was present (150 µg) the women taking those tablets should supplement their diets to obtain the additional 70 µg. Barkley Decl. ¶ 54. This can be obtained through the use of iodized salt. Azur has failed to show that any possible misstatements on the TRIGEN Products regarding B12 or iodine are material or could possibly result in extreme or serious damage to anyone taking the TRIGEN Product.

LaboVal performed one Assay Test on the Folivane™ product and provided the results with Mr. Bakhshi's Declaration. D.I. 18, Ex. H. Mr. Bakhshi alleges that LaboVal's testing showed that the amount of iodine was below the USP guidelines (119 µg instead of 150 µg) and that the amount of ascorbic acid was above the USP guidelines (140 µg instead of 120 µg), which he claimed was 125%. When faced with the correct upper limit for ascorbic acid, Mr. Bakhshi admitted that the amount of the ascorbic acid in the Folivane™ tablets was within the USP guidelines (116.6%). Barkley Decl. ¶ 52. In light of the deficiencies in the Assay Tests performed by LaboVal, it is questionable whether the 119 µg/tablet tested for iodine is accurate. Barkley Decl. *passim.* However, even if it is accurate, Azur has not shown nor alleged that this difference is material.

c. Azur Has Failed to Show TRIGEN's DHA Capsule were Tested or that the Test Results Are Material

Viva tests the DHA content of the raw DHA material it receives and separately tests the DHA content of the DHA capsules manufactured for the TRIGEN Products. Ko

Decl. ¶ 21, Exs. D - F (specifically Fatty Acid - DHA), Barkley Decl. ¶ 58. Viva's approved tests indicate that the DHA content of the TRIGEN DHA capsules are acceptable and within the range of 272.3 mg - 295 mg/capsule. Ko Decl. Exs. D - F.

Azur relies on Mr. Reuther's declaration and exhibits to allege that the DHA capsules included in the relevant TRIGEN Products contain less than the labeled amount of DHA. Mr. Reuther's declaration and exhibits do not conclusively show that the DHA levels of the TRIGEN Products are low. Exhibit A of Mr. Reuther's declaration contains no verifiable information to show the tested samples were from TRIGEN. D.I. 19, Ex. A. The exhibit does not include a lot number for the DHA capsules or for the Taron™ DHA tablets the DHA capsule came with. Additionally, Mr. Reuther admits he has no personal knowledge of the origins of the capsules. D.I. 19, ¶ 8. Instead he relies on Martek Biosciences Corporation to identify the capsules. *Id.* Furthermore, without an RDA for DHA, there is no indication that the allegedly low amount of DHA is material.

Mr. Reuther's second test of Taron™ DHA capsules and his test of Folivane™ capsules fare no better. The Report of Analysis included in Exs. C and D fail to identify the lot number of the: 1) DHA capsules themselves; or 2) the products the DHA capsules are associated. D.I. 19, Exs. C and D. Even Mr. Reuther's Ex. E (a photocopy of two sides of the Folivane™ carton) fails to identify the lot number of the Folivane™ product allegedly tested. *Id.* Ex. E. Each of the Reports of Analysis indicates that the measures made are subject to uncertainty but they do not provide any value for the uncertainty. *Id.* Exs. C and D ("[u]ncertainty can be obtained upon request").

Finally, Azur fails to allege or show that an 11% - 13% discrepancy in the DHA amounts is material. Since no RDA for DHA has been established, it is difficult, if not

impossible, for Azur to allege that an allegedly low value for DHA is material. Many doctors recommend 200 - 300 mg/day for pregnant women. Barkley Decl. ¶ 61. Mr. Reuther's results of between 216.0 - 222.4 mg of DHA exceeds the minimum level recommended by these doctors and the allegedly low values are immaterial.

2. Azur Has Failed to Show a False Statement in Commercial Advertisement or Promotion

In order for a statement to be a commercial advertising or promotion and fall under the Lanham Act in this circuit, the statement must be: (1) commercial speech; (2) intended to influence consumers to purchase the goods or services; and (3) disseminated sufficiently to the relevant purchasing public. *Chamilia*, 2007 U.S. Dist. LEXIS at *21 (citing *Gmurzynska v. Hutton*, 355 F.3d 206, 210 (2d Cir. 2004) and *Fashion Boutique of Short Hills, Inc. v. Fendi USA, Inc*., 314 F.3d 48, 56-58 (2d Cir. 2002)). Commercial speech is "usually defined as speech that does no more than propose a commercial transaction." *United States v. United Foods, Inc.*, 533 U.S. 405, 409 (2001).

a. Azur has Failed to Show TRIGEN Commercially Advertised or Promoted its Products as Biphasic

Azur has alleged that TRIGEN falsely claims, labels, markets, and advertises, Taron™ DHA and Folivane™ as biphasic. D.I. 16, pp. 4-6. However, Azur fails to identify where TRIGEN has made this statement as part of a commercial advertisement or a promotion. Instead, Azur states "TRIGEN makes [this] representation[ ] on its product packages and in its statements to drug-publishing services for listing its products on those services' databases." D.I. 16, p. 6.

(i) "Biphasic" Does Not Even Appear on Either the Taron™ or Folivane™ Package

A review of the cartons of the Taron™ DHA and Folivane™ products clearly shows that neither carton contains a biphasic statement or even mentions the word biphasic. Hudy Decl. Exs. A & C. Even Azur's expert, Mr. Bakhshi admitted this and corrected paragraphs 13 and 28 of his declaration to change carton (¶ 13) and package (¶ 28) to product insert. Barkley Dec. ¶ 25, Ex. B, ¶¶ 13, 28. Obviously, neither the Taron™ nor the Folivane™ packages can contain a false biphasic statement. Azur's allegations are completely unfounded.

(ii) "Biphasic" Statement in Product Inserts are not Commercial Advertisements

Included inside each of the Taron™ DHA and Folivane™ packages is a product insert which includes the following statement:

> The formulation has been designed to avoid interference of calcium and iron absorption through a pH-dependent biphasic release of these minerals at different sites in the gastrointestinal tract. The immediate-release iron dissolves at gastric pH, while the delayed-release enteric coated granules dissolve in the small intestine at a pH of 5.5 or higher.

Hudy Decl. Exs. B & D. As an initial matter, this statement does not claim the product is biphasic, but rather states that it has been designed to have a biphasic release. As such, Azur's alleged testing of the biphasic nature of the TRIGEN Products is not relevant to the biphasic statement. Even if the Court finds that this statement makes a biphasic claim, the testing performed by both Azur and Viva show that not all of the iron and all of the calcium is released at the same time. The TRIGEN Products are therefore biphasic. Barkley Decl. ¶¶ 42-43, 46. Additionally, Azur cannot claim these statements are false and actionable under the Lanham Act, because product inserts are not

commercial advertisements or promotions. "Advertising or promotion implies that the statements are made to influence a consumer in his or her choice to purchase a product. Statements made inside the product's packaging, available to consumers only after the purchase has been made, do not affect the choice to purchase, that choice having been made at an earlier point. The court thus concludes that Norelco's package inserts are not "commercial advertising or promotion" as that phrase is used in section 43(a)." *Gillette Co. v. Norelco Consumer Prods. Co.*, 946 F. Supp. 115, 135 (D. Mass. 1996). See *Eon Labs Manufacturing, Inc., v. Watson Pharmaceuticals, Inc.*, 164 F. Supp. 2d 350, 361 (S.D.N.Y. 2001) (Indeed, "it is not readily comprehensible why or how consumers or pharmacists would reasonably rely on . . . the product inserts . . . particularly when those inserts were only accessible after opening" the package.).

(iii) "Biphasic" Statements Made to Drug Publishing Companies are not Commercial Advertisements or Promotion

TRIGEN has submitted information pertaining to its Taron™, Taron™ DHA, and Folivane™ products to drug publishing services such as Gold Standard, First Databank, and Medispan. Included with each of these submissions was a draft copy of the carton label and the product insert. The biphasic statement only appears on the product inserts.

Azur has failed to allege or show that the biphasic statement contained in the product inserts and submitted to the drug publishing services are: 1) commercial speech (*i.e.*, does no more than propose a commercial transaction); 2) intended to influence consumers to purchase the TRIGEN Products; or 3) has been disseminated sufficiently to the relevant purchasing public. Since Azur has not even alleged these elements, it cannot show a clear or substantial likelihood of success that TRIGEN made a false biphasic

statement to the drug publishing services which is actionable under the Lanham Act claim.

b. Azur has Failed to Show that the Labels on the TRIGEN Packages are Commercial Advertising or Promotions

Azur has alleged that TRIGEN falsely claims, labels, markets, and advertises "that the TRIGEN Products contain the identical ingredients and ingredient strengths as the Gesticare® Products."[10] D.I. 16, pp. 4-6. Azur fails to allege or show where TRIGEN has made a comparison between the Gesticare® and the TRIGEN Products.

Both Mr. Bakhshi and Mr. Reuther allege that TRIGEN's listing of the amounts of certain ingredients contained in the Taron™ DHA, Folivane™, or DHA capsules is false. D.I. 16, p. 5, D.I. 18, ¶¶ 33-34; D.I. 19, ¶¶ 8 - 22. Even if these accusations are based on reliable tests, neither of these individuals, nor Azur, allege that TRIGEN has made these statements as part of a commercial advertisement or a promotion.

TRIGEN includes its listing of ingredients in the following three places: 1) in the product inserts, 2) on the packages of the products, and 3) on the product inserts and sample package labels that were submitted to the drug publishing services. Not one of these should be considered as commercial advertising/ promotion under the Lanham Act.

As previously explained, statements made on product inserts, unavailable to the consumers until after the customer has purchased the product, do not affect the choice to purchase, and are not commercial advertising or promotion under section 43(a). *Gillette*

[10] In a similar manner, Azur claims that TRIGEN "falsely informed the market that its product was equivalent to Azur's." D.I. 16, p. 2.

Co., 946 F. Supp. 135. Accordingly, the listing of the ingredients on the package inserts does not give rise to a claim under the Lanham Act.

Each of the TRIGEN Products are prescription products which only become available to the end customer after the customer has purchased the product. Hudy Decl. ¶¶ 15, 17. As such, the listing of the ingredients on the package label are "available to consumers only after the purchase has been made, do not affect the choice to purchase, that choice having been made at an earlier point." *Gillette Co.* 946 F. Supp. 135. Under the analysis performed by the *Gillette* Court, statements made on the packaging of prescription products are not commercial advertising/promotion under the Lanham Act.

Finally, Azur has failed to allege or show that the listing of ingredients on the product packaging or the submissions to the drug publishing services: 1) does no more than propose a commercial transaction; 2) is intended to influence consumers to purchase the TRIGEN Products; or 3) has been disseminated sufficiently to the relevant purchasing public. Accordingly, Azur cannot show a clear or substantial likelihood of success that TRIGEN made a false statement, actionable under the Lanham Act, by listing the product's ingredients on the product's package, the product inserts, or by providing the ingredients to the drug publishing services.

IV. SUFFICIENTLY SERIOUS QUESTIONS/BALANCE OF HARDSHIPS TEST IS NOT APPLICABLE, AND IF IT WERE IT DOES NOT FAVOR AZUR

Under the higher standard Azur's PI Motion is subject to, the "sufficiently serious questions going to the merits to make them a fair ground for litigation, and a balance of hardships tipping decidedly in the moving party's favor" criteria for a preliminary injunction is unavailable. *Ponterio*, 2007 U.S. Dist. LEXIS *42 n. 29. However, even if it were available, Azur would still be required to show a clear or substantial likelihood of

success on the merits, or that extreme or very serious damage will result from a denial of preliminary relief. *Tom Doherty Assocs.*, 60 F.3d at 34. Azur's PI Memo fails to show either.

Azur cannot show a clear or substantial likelihood of success on the merits for at least the following reasons: 1) Azur has failed to show irreparable harm; 2) Azur's dissolution testing is unreliable and questionable; 3) Azur's Assay Testing is questionable; 4) Azur has failed to show (or even allege) that any allegedly false statement was material; 5) Azur has failed to show (or even allege) that TRIGEN made any allegedly false statement as a part of a commercial advertising or promotion; and 6) Azur has failed to show that any allegedly false statement was disseminated sufficiently to the relevant purchasing public. Also there is no extreme or very serious damage alleged.

V. AZUR'S GMP, MISSING LOT NUMBER, AND EPA ALLEGATIONS ARE WITHOUT MERIT

The results of Mr. Bakhshi's testing allegedly show variations in the amounts of two of the ingredients in the Taron™ DHA samples tested. Mr. Bakhshi uses these variations to conclude that the Taron™ DHA products are not manufactured in accordance with current Good Manufacturing Practices ("cGMP"). D.I. 18, ¶ 35. Mr. Bakhshi bases this conclusion exclusively on his testing of iodine and B12. *Id.* Mr. Bakhshi makes this conclusion without considering: 1) the standard operating procedures of the manufacturing facility, 2) the certifications of the manufacturing facility, 3) the

consistency of the test results for the other ingredients in the tested tablets.[11] As aptly showed by David Ko's Declaration, the TRIGEN Products are manufactured in accordance with cGMP. Ko Declaration, ¶¶ 10-12, 21-28. Barkley Dec. ¶ 60. Mr. Bakhshi's cGMP accusations regarding the TRIGEN Products are unwarranted and speculative.

Finally Mr. Bakhshi expresses "extreme concern" that the blister packs of TRIGEN's Folivane™ Product do not include one lot number and expiration date for the Folivane™ tablet and a separate lot number and expiration date for the included DHA capsule. Mr. Bakhshi could not justify that concern by citing to an FDA regulation that requires different lot numbers and expiration dates for the tablet and the capsule. Barkley Decl. ¶¶ 63. Contrary to Mr. Bakhshi's unsupported opinion, providing one lot number/expiration date on a blister pack which contains a tablet and a DHA capsule is perfectly acceptable and in accordance with FDA requirements, as long as the company maintains records which correlate the lot number and expiration dates on the packages with the lot numbers and expiration dates from the manufacturer of the product. McHenry Decl. ¶¶ 6 - 14.

Mr. Reuther expressed a concern that the labels for the DHA capsules only included the amount of DHA included in the capsule, but did not include the amount of EPA included in the capsule. D.I. 19 ¶¶ 12, 16, 21. Azur has not argued that this is a materially false statement. This small amount of EPA would not pose a threat to the

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[11] Mr. Bakhshi's Taron™ DHA tests showed general agreement regarding the amounts of: ascorbic acid (151 mg, 152 mg, 150 mg), iron (28 mg, 28 mg, 28 mg), zinc (14.5 mg, 14.5 mg, 14.9 mg), folic acid (1 mg, 1 mg, 0.97 mg), Niacin (20.6 mg, 20.8 mg, 20.8 mg), Vitamin B6 (52.6 mg, 52.3 mg, 52.3 mg), Vitamin B2 (3.4 mg, 3.5 mg, 3.3 mg) and Vitamin B1 (3.2 mg, 3.8 mg. 2.8 mg).

users of the product. Barkley Dec. ¶ 62. Even the Gesticare® Products include small amounts of EPA not listed on the Gesticare® labels. D.I. 20, Ex. D, p. 1; Ex. E, p. 1 (Gesticare® with DHA contains less than 0.625 mg of EPA"); Ex. G, p. 2. Neither Mr. Reuther nor Azur has shown that TRIGEN falsely represented this fact in commercial advertising or promotion. Neither Mr. Reuther nor Azur has shown TRIGEN has advertised that the TRIGEN Products do not contain EPA in: 1) commercial speech (*i.e.*, does no more than propose a commercial transaction); 2) intended to influence consumers to purchase the TRIGEN Products; or 3) has been disseminated sufficiently to the relevant purchasing public. Since Azur has not even alleged these elements, it cannot show a clear or substantial likelihood of success that TRIGEN made a false statement regarding EPA which is actionable under the Lanham Act claim.

CONCLUSION

For all of the foregoing reasons, Defendant TRIGEN Laboratories, Inc. respectfully request that the Court DENY in its entirety Plaintiff Azur Pharma Inc's Motion for a Preliminary Injunction.

Respectfully submitted,

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Dated: April 2, 2010

Attorneys for TRIGEN Laboratories, Inc.

CERTIFICATE OF SERVICE

I hereby certify that on April 2, 2010 I served the forgoing TRIGEN Laboratories Inc.'s Memoranda of Law in Opposition to Azur's Motion for Preliminary Injunction and the Declarations of Kevin Hudy, Aaron Barkley, Kristen McHenry, and David Ko upon the following counsel via the ECF filing system in accordance with Local Civil Rule 5.2:

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